## Bayer HealthCare Consumer Care Division

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May 10, 2005

Office of Special Nutritionals Center for Food Safety and Applied Nutrition U.S. Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740-3835



Subject: 30-Day Post Market Notification for Structure/Function Claims; One-A-Day® Cholesterol Plus™ Dietary Supplement

Dear Sir or Madam:

Bayer Consumer Care Division submits the information in this notification pursuant to Section 403(r)(6) of the Food, Drug and Cosmetic Act as notice of marketing structure/function claims on the product label of One-A-Day® Cholesterol Plus<sup>™</sup> Dietary Supplement.

PRODUCT NAME	One-A-Day <sup>®</sup> Cholesterol Plus <sup>™</sup>
NAME /ADDRESS OF	Bayer HealthCare
DISTRIBUTOR	Consumer Care Division
	36 Columbia Road
,	P. O. Box 1910
	Morristown, New Jersey 07962-1910
NAME OF DIETARY	One-A-Day <sup>®</sup> Cholesterol Plus <sup>™</sup>
INGREDIENT/SUPPLEMENT	Multivitamin/Multimineral Supplement
(SUBJECT OF THE	
STATEMENT)	
TEXT OF STATEMENT BEING	
MADE	
Top Panel of Carton	Complete Multivitamin specially designed to
i i	support Cholesterol and Blood Pressure
,	Only complete multivitamin with Policosanol to
	help maintain healthy cholesterol levels. **
	Folic Acid and Calcium to support healthy
,	blood pressure. <sup>‡*</sup>
,	B6, B12, Folic Acid, Vitamin C, and Vitamin E
	to support hearth health.*
5 <sup>th</sup> Panel of Carton	Helps Maintain Healthy Cholesterol <sup>‡</sup> And Blood
,	Pressure <sup>‡</sup> Levels.*
	Helps Maintain Healthy Cholesterol & Blood
	Pressure
	Supports a Healthy Heart
1	Cholesterol and blood pressure levels already
	within the normal range

Bayer HealthCare LLC Consumer Care Division 36 Columbia Road P.O. Box 1910 Morristown, NJ 07962-1910

Phone: (973) 408-8046 Fax: (973) 254-4875

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Right Panel of Carton	<ul> <li>Key Ingredients To Help Support Your Health*</li> <li>CHOLESTEROL &amp; BLOOD PRESSURE‡: Policosanol, Folic Acid, Calcium</li> <li>HEART HEALTH: B6, B12, Folic Acid, Vitamin E, Vitamin C</li> <li>JOINTS &amp; BONES: Vitamin C, Vitamin D, Calcium, Magnesium, Zinc</li> <li>IMMUNITY: Beta Carotene, Vitamin C, Vitamin E, Zinc</li> <li>PHYSICAL &amp; MENTAL ENERGY: B6, B12, Niacin, Thiamin, Riboflavin, Pantothenic Acid, Biotin, Magnesium</li> <li>‡ Cholesterol and blood pressure levels already within the normal range.</li> </ul>
Back of Carton	Helps you maintain healthy cholesterol and blood pressure levels.* Keeping cholesterol and blood pressure levels within a normal range helps
,	control two of the key risk factors for heart disease. That's why One-A-Day ® developed new
	Cholesterol Plus ™, a complete multivitamin plus heart-health supporting nutrients, including
,	Policosanol, to help maintain healthy cholesterol and blood pressure levels already within the normal range.* One-A-Day ® Cholesterol Plus ™ can help you keep your levels healthy.
*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.	

In accordance with 21 CFR 101.93, the information contained in this notification is complete and accurate. Bayer Consumer Care Division has substantiation on file that the statements are truthful and not misleading. This notification is comprised of an original and two (2) copies.

Should you have any questions or need any additional information, please contact the undersigned at 973-408-8046 or Catherine Fish at 973-254-4793.

Sincerely,

William R. Walsh

Senior Associate Director, Regulatory Affairs

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**BAYER HEALTHCARE** 

CONSUMER CARE DIVISION